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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/845,923 | 04/30/2001 | Patrick Kennedy | 1022-11 | 4246 |

7590

04/01/2004

Mr Jackie J Schwartz
1350 BROADWAY
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New York, NY 10018-7702

EXAMINER

PATTEN, PATRICIA A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1654

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/845,923 | KENNEDY, PATRICK | |
| | Examiner | Art Unit | |
| | Patricia A Patten | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-22, 24-28 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8, 10-19, 21-22, 24-28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-8, 10-22, 24-28 and 30-32 are pending in the application.

Claims 1-3 and 20 were previously withdrawn from further consideration as they are drawn to a non-elected invention (Paper No. 3).

Although Applicants state that only claims 1-8, 10-22, 24-28 and 30-32 are pending in the application, it is noted that in the most recent response from Applicants, the presentation of claims lists claim 9 as being '(original)' while this claim should be presented as '(cancelled)'. This is considered an inadvertent error. A notice of non-compliant amendment was not sent to Applicant, so as to expedite prosecution of the case. It can be found in Applicant's comments pertaining to the pending claims, as well as prosecution history, that claim 9 is indeed cancelled, and will not be further treated on the merits. It is requested that Applicants, upon sending any additional correspondence to the Office, especially upon sending any new amendments to the claims, include this claim in the listing of claims as being '(cancelled)' in order to clarify the record.

Claims 4-8, 10-19, 21-22, 24-28 and 30-32 were presented for examination on the merits.

Applicant's arguments which are directed solely to the previous rejections are moot in light of the new rejections *infra*.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-8, 10-19, 21-22, 24-28 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

All of these claims either recite, or depend upon a claim that recites 'carrier able to abrade the site and circulate at least one of a toxin and venom out from said site'. After careful review of the disclosure, it cannot be found in the Instant specification as filed, any teaching that indicates that the carrier performs such functions. Therefore, it is deemed that Applicant was not in possession of such carriers absent sufficient evidence to the contrary.

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Claims 4-8, 10-19, 21-22, 24-28 and 30-32 are further newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a carrier does not reasonably provide enablement for a carrier which is able to abrade the site and circulate at least one of a toxin and venom'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or

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unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

In the Instant case, the claims state 'and a carrier able to abrade the site and circulate at least one of a toxin and venom out from said site'. The claims are not enabling for any of the carriers listed; i.e., emollient, beeswax or gum for example, because Applicant has not demonstrated in the Instant specification which of these carriers actually has these effects.

Further, there is not one working example in the Specification which clearly demonstrates that any of the carriers such as gum or a lubricant, will actually perform commensurate in scope with the claimed invention. Absent such evidence, one must consider the guidance provided by the instant specification and the prior art of record: The carriers as listed in the claims; i.e., stone, seed shell and emollients for example, were not known in the art for circulating toxins out of a wound. What is known in the prior art about emollients for example, is that these types of suspensions are made in order to texturize liquid products for ease of topical delivery. Again, emollients are not known in the art for abrading sites of insect bites and circulating toxins and venom out from said sites. The skilled artisan would not know how to use an emollient, or any of the other listed carriers, in the manner recited by the claims.

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The state of the art is unpredictable. Applicants are stating that the composition comprises a carrier which actually abrades the skin, and circulates a toxin or venom out of the site of an insect bite or sting. Therefore, even if Applicants had described any compound which would actually contact the toxin or venom produced by an insect bite or sting, the compound would then need to circulate the toxin or venom away from the site of the bite or sting. ***There are no such compounds as can be found in the prior art*** and no compounds/carriers which have been taught in the Instant specification, or even eluded to which would perform such a function. It is conceivable that there may be specific compounds known in the art for cleaving specific toxins (i.e., perhaps urea or EDTA) but these compounds will not physically leave (or circulate out) the site of the sting unless manually removed from said site by adsorption or suction as two examples.

Therefore, in light of the unpredictability in the art concerning the claimed carriers in performing the claimed functions, precludes the making and use of the claimed compositions. The skilled artisan would need to perform expensive, rigorous trial and error protocols to ascertain what carriers, if any, perform the functions as required by the claims, thus leading to undue experimentation. It is further deemed that Applicants were not in possession of such carriers at the time the Invention was made, and thus, the new limitations are deemed New Matter.

Claims are free of the art, as indicated *supra*, no compounds are found in the art which perform the functions of the carriers as recited by the claims.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0968. The fax phone


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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia A Patten
Examiner
Art Unit 1654

3/22/04

A handwritten signature in black ink, appearing to read 'Patricia A. Patten', with a stylized flourish at the end.

PATRICIA PATTEN
PATENT EXAMINER